MAY 27 2004

Special 510(k) Summary

Proprietary Name:	Avon™ Extra-small Patello-femoral Replacement
Common Name:	Patello-femoral Replacement
Classification Name and Reference:	21 CFR 888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis
Proposed Regulatory Class:	Class II
Device Product Code:	OR (87) KRR
Predicate Proprietary Name:	Avon™ Small Patello-femoral Replacement
Predicate Regulatory Class:	21 CFR 888.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis
Predicate Product Code:	OR (87) KRR
For Information contact:	Margaret F. Crowe Howmedica Osteonics Corp. 325 Corporate Drive Mahwah, New Jersey 07430 Phone: (201) 831-5580 Fax: (201) 831-6038

Description/Technological Comparison

The Avon™ Patello-femoral Joint Prosthesis (cleared for marketing in K010100 and K020841)

is intended to be used in the replacement of the patellofemoral joint in patients with degenerative arthritis of the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists. The current system consists of cobalt-chromium femoral components available in three sizes (small, medium, and large), and all-polyethylene components available in three sizes (small, medium, and large). These components are intended to be implanted using bone cement.

It is the intention of Stryker Howmedica Osteonics to introduce an extra-small Avon™ Patello-femoral replacement component. The extra-small Avon™ femoral component differs from the previously released small Avon™ femoral component in the following ways:

1. The width of the patellar flange is reduced by 3mm (small 46.5mm; extra-small: 43.5mm)
2. The intra-condylar distal flange height is reduced by 1.5mm (small 19.5; extra-small 18.0mm)

This component is also intended to be implanted using bone cement.

Intended Use

The Avon™ Extra-Small Patello-femoral Replacement component is a single-use device intended for replacement of the femoral side of the patello-femoral joint.

The Avon™ Patello-femoral Joint Replacement is intended to be used in cemented patellofemoral arthroplasty in patients with degenerative arthritis in the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 27 2004

Ms. Lorraine T. Montemurro
Regulatory Affairs Manager
Stryker Howmedica Osteonics
325 Corporate Drive
Mahwah, New Jersey 07430

Re: K041160
Trade/Device Name: Line Extension to Avon™ Patello-femoral Joint Replacement – Extra-Small Femoral Component
Regulation Number: 21 CFR 888.3540
Regulation Name: Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis
Regulatory Class: II
Product Codes: KRR
Dated: April 30, 2004
Received: May 3, 2004

Dear Ms. Montemurro:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K041160

Indications for Use

510(k) Number (if known):
Device Name: Line Extension to Avon™ Patello-femoral Joint Replacement – Extra-Small Femoral Component

Indications For Use:

The Avon™ Patello-femoral Joint Replacement is intended to be used in cemented patellofemoral arthroplasty in patients with degenerative arthritis in the distal femur and patella, patients with a history of patellar dislocation or patella fracture, or patients with failed previous surgery (arthroscopy, tibial tubercle elevation, lateral release) where pain, deformity or dysfunction persists.

These components are single use only and are intended for implantation with bone cement.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark A. Milhouse

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041160